CERTIFICATE OF EXPRESS MAIL

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I hereby certify that this paper or fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to: MS Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria VA, 22313-1450.

Paula S. Sinkhart

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Daniel N. HEINTZ Yunhau N. JENG

Serial No.: To be assigneed

Filed: Herewith

For: NON-AQUEOUS INJECTABLE

FORMULATION PREPARATION WITH

pH ADJUSTED FOR EXTENDED RELEASE OF SOMATOTROPIN

Group Art Unit: To be assigned

Examiner: To be assigned

Atty. Dkt. No.: 11916.0046.DVUS02

INFORMATION DISCLOSURE STATEMENT

MS PATENT APPLICATION

Commissioner for Patents P.O. Box 1450 Alexandria VA, 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as

defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first

Official Action reflecting an examination on the merits, and hence is believed to be timely filed

in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the

filing of this Information Disclosure Statement, however, should any additional fees under 37

C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the

Commissioner is authorized to deduct said fees from Deposit Account No.

01-2508/**11916.0046.DVUS02**.

This application is a divisional application of Serial No. 09/894,058, filed June 28, 2001

and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37

C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously

cited by or submitted to the Patent and Trademark Office in prior application Serial No.

09/894,058.

Applicant respectfully requests that the listed documents be made of record in the present

case.

Respectfully submitted,

Matthew L. Madsen

Reg. No. 45,594

Patent Agent for Assignee

Matthews Made

MONSANTO TECHNOLOGY LLC

HOWREY SIMON ARNOLD & WHITE, LLP 750 Bering Drive Houston, Texas 77057-2198

(713) 787-1400

Date:

October 22, 2003

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Form PTO-1449 (modified)		Atty. Docket No. Serial No. To be assigne 11916.0046.DVUS02		
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT		Applicant: Daniel N. Heintz Yunhua N. Jeng		
(Use several sheets if necessary)		Filing Date: Herewith	Group: To be assigned	
U.S. Patent Documents See Page 1-2	1	Patent Documents see Page 2-3	Other Art See Page 3	

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A 1	4,816,568	3-28-89	Hamilton et al.	530	399	5-16-86
	A2	4,857,506	8-15-89	Tyle	514	12	01-12-87
	A3	4,917,685	4-17-90	Viswanathan et al.	604	891.1	5-16-86
_	A4	4,977,140	12-11-90	Ferguson et al.	514	12	03-23-89
	A5	5,034,229	07-23-91	Magruder et al.	424	422	12-13-88
	A6	5,037,420	08-06-91	Magruder et al.			
	A7	5,096,885	03-17-92	Pearlman et al.			
	A8	5,219,572	06-15-93	Sivaramakrishnan et al.	424	438	07-25-91
	A9	5,356,635	10-18-94	Raman et al.	424	484	07-13-93
•	A10	5,359,030	10-25-94	Ekwuribe	530	303	05-10-93
	A11	5,399,489	03-21-95	Krivi	435	69.4	11-12-92
	A12	5,438,040	08-01-95	Ekwuribe	514	3	07-19-94
	A13	5,474,980	12-12-95	Mitchell			
	A14	5,520,927	05-28-96	Kim et al.	424	450	07-14-94
	A15	5,607,691	03-1997	Hale			
	A16	5,612,315	03-18-97	Pikal et al.	514	21	07-06-92
	A17	5,631,277	05-1997	Harbour	514	12	
	A18	5,681,811	10-28-97	Ekwuribe	514	8	07-31-95
	A19	5,739,108	04-14-98	Mitchell	514	12	12-11-95
	A20	5,744,163	04-28-98	Kim et al.	424	489	11-13-96
	A21	5,773,588	06-1998	Owsley			
	A22	5,801,141	09-01-98	Steber			
	A23	5,849,704	12-15-98	Sørensen et al.	514	12	06-02-95

Examiner:	DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. D cket No. 11916.0046.DVUS02	Serial No. To be assigned	
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U.S. Patent Documents See Page 1-2		atent Documents Page 2-3	Other Art See Page 3	

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Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A24	5,972,370	10-1999	Echenhoff	424	424	
	A25	5,986,073	11-16-99	Storrs et al.	530	419	12-21-95
	A26	6,086,918	07-2000	Stern	424	474	
	A27	6,162,258	12-19-00	Scarborough			
	A28						

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 97/03692	02-06-97	WIPO	A61K	38/27	
	B2	EP 0 216 485	04-01-87	EP	C07G	15/00	
	В3	WO 93/13792	07-22-93	WIPO	A61K	37/02	
	B4	WO 93/19773	10-14-93	WIPO	A61K	37/02	
	B5	WO 93/12812	07-08-93	WIPO	A61K	37/36	
	В6	EP 0 523 330 A1	01-20-93	EP	A61K	9/00	,
	В7	WO 00/13674	03-16-00	WIPO	A61K	9/20	
-	B8	EP 0 278 103 A	08-17-88	EP			
	B9	EP 0 303 746 A1	02-22-89	EP			
	B10	EP 0 374 120 A	06-20-90	EP			
	B11	EP 0 913 177 (Abstract)	05-06-99	EP			
	B12	JP 3086834 (Abstract)	4-11-91	JP			
	B13	WO 89 09614 A	10-19-89	WIPO			

Examiner:	DATE CONSIDERED:
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Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B14	WO 97/29767	08-21-97	WIPO			· <u> </u>
	B15	WO 98/29131	07-09-98	WIPO			

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Katakam, Manohar: Use of non-ionic surfactants to stabilize recombinant human growth hormone and to develop its sustained release formulation, DISS. ABSTR. INT., vol. 57, no. 5, 1996, page 3149.

EXAMINER: DATE CONSIDE

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